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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,046	09/25/2006	Nnochiri N. Ekwuribe	014811-673.119US	8968

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,046	EKWURIBE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,15-30 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,15-30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Response filed March 18, 2009 is acknowledged. Claims 10-14 are canceled. New claim 32 is presented. Accordingly, claims 1-9, 15-30 and 32 are now under consideration.

A complete list of all co-pending and related application for the inventor Nnochiri Ekwuribe is again requested when Applicants respond to this Office Action.

Those rejections set forth in previous Office Actions that are not herein reiterated are withdrawn. The following objections and rejections constitute the only objections and rejections presently applied to the instant claims.

The drawings are objected to because the graph depicted in Figure 22 uses the terms "@&&" having "##" underneath. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The abstract of the disclosure is objected to because it is not directed to the subject matter presently under consideration. Correction is required. See MPEP § 608.01(b).

Applicants are reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are shown on page 30.

Claims 15-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Newly amended claim 15 lacks clarity with respect to the recitation characterized as "(a)," "at least **one component** selected from the group consisting of a **first and second component** wherein the first component comprising one or more of the therapeutic agents formulated for release in the stomach, and the second component comprising one or more of the therapeutic agents formulated for release in the **small intestine or distal portion of the small intestine**, wherein the therapeutic agents for the distal portion of the small intestine is a 4-APAA compound azo bonded to a 5-ASA compound or a combination of 4-APAA and 5-ASA compounds…"

Clarification is required.

Claims 1-9, 15-30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. See *In re Rasmussen*, 211 USPQ 323 (CCPA 1981).

Applicants are expected to specifically point out the support in the specification for all amendments made to the claims. See MPEP 714.02 and 2163.06.

The present amendments to the claims appear to represent a shift away from the originally claimed pharmaceutical compositions. See MPEP 819.

Amended claim 1 now requires at least one agent recited from among the therapeutic agents selected from the group consisting of:

azo-bonded 4-APAA compound;

non-azo bonded 4-APAA compound;

azo-bonded 5-ASA compound;

non-azo bonded 5-ASA compound;

and **now adds a second required selection** of at least one therapeutic agent from from the group consisting of:

4-APAA compound azo bonded to a 5-ASA compound and
a combination of 4-APAA compound and a 5-ASA compound.

Original claim 1 required "two or more therapeutic agents selected from the group consisting of:

azo-bonded 4-APAA compound;

non-azo bonded 4-APAA compound;

azo-bonded 5-ASA compound;

non-azo bonded 5-ASA compound; and

4-APAA compound azo bonded to a 5-ASA compound."

Amended claim 15 now requires **at least two therapeutic agents** selected from the group consisting of:

azo-bonded 4-APAA compound;

non-azo bonded 4-APAA compound;

azo-bonded 5-ASA compound;

non-azo bonded 5-ASA compound;
4-APAA compound azo bonded to a 5-ASA compound and
a combination of 4-APAA compound and a 5-ASA compound,

such that any therapeutic agents may be released in the stomach, small intestine and colon, but release in the "distal portion of the small intestine" is limited to a 4-APAA compound azo-bonded to a 5-ASA compound or a combination of 4-APAA and 5-ASA compound.

Amended claims 16-29 and new claim 32 now optionally require a 4-APAA compound azo-bonded to a 5-ASA compound for release in the colon. No 4-APAA compound azo-bonded to a 5-ASA compound for release in the colon is noted in the instant specification. This limitation represents new matter.

No claim is allowed.

Applicants' Amendment necessitated the new grounds of rejection presented in this Office Action. **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 5, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614